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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,436	08/16/2005	Kazuo Kobayashi	081356-0224	8917

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FOLEY AND LARDNER LLP
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WASHINGTON, DC 20007

EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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06/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,436	Applicant(s) KOBAYASHI ET AL.	
	Examiner NANCY VOGEL	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 5-93, 97-107 and 114-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 94-96 and 108-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/05, 9/6/07, 11/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 5-93, 97-107, 114-122 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/7/08.

Applicant's election without traverse of Group I, claims 1-4, 94-96 and 108-113, species OCH1 gene for group I, URA3 gene for claim 96, and OCH1 gene for claim 108, in the reply filed on 3/7/08 is acknowledged.

Information Disclosure Statement

Receipt of the Information Disclosure Statements on 8/16/05, 9/6/07, and 11/28/05, is acknowledged.

The documents listed on the Information Disclosure Statement filed 8/16/05 have not been received, and therefore they have not been considered and have been crossed through.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/00856 (cited by applicants).

WO 02/00856 disclose a method for producing proteins that have a mammalian-type sugar chain by introducing vectors that express alpha-1,2, mannosidase into a methylotrophic yeast (*Pichia pastoris*), and in which the OCH1 genes are deactivated (see claims, Example 3, abstract). The reference discloses that any methylotrophic yeast may be used (see Description, which states in the Summary: "Strains of a methylotrophic yeast which can be modified using the present methods include, but are not limited to, yeast strains capable of growth on methanol such as yeasts of the genera *Candida*, *Hansenula*, *Torulopsis*, and *Pichia*. Preferred methylotrophic yeasts are of the genus *Pichia*. Especially preferred are *Pichia pastoris* strains GS115 (NRRLY-15851), GS190 (NRRLY-18014), PPFI (NRRL Y18017), PPY120H, yGC4, and strains derived therefrom. Methylotrophic yeast strains which can be modified using the present methods also include those methylotrophic yeast strains which have been engineered to express one or more heterologous proteins of interest. The glycosylation on the heterologous proteins expressed from these previously genetically engineered strains can be reduced by transforming such strains with one or more of the vectors of the present invention").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 94-96, 108-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/00856 in view of Strauss et al. (20070077642).

WO02/00856 is cited essentially for the reasons set forth above.

The difference between the reference and the instant claims is that a particular methylotrophic yeast, i.e. *Ogataea minuta*, is used. However, Strauss et al. disclose the use of the *Ogataea minuta* strain for production of recombinant proteins (see para 0067). It would have been obvious to have utilized the known host yeast strain *Ogataea minuta* strain, in the method disclosed by WO02/00856, since WO02/00856 disclose that any methylotrophic yeast strain may be used, and since Strauss et al. disclose the known *Ogataea minuta* strain, which is a methylotrophic yeast strain. In the absence of unexpected results, it is considered that the use of one particular known methylotrophic yeast strain in the known method would have been obvious. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 95, 96, 109-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application discloses particular yeast strain IFO10746 that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F. R. 1,801-1.809, in the form of a declaration of applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the

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biological material which has been deposited is the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 94-98, 108-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 94, 108, and by dependence claims 2-4, 95, 96, and 109-113, are vague and indefinite in the recitation of "capable of", since this phrase refers to a latent ability; it is unknown whether the ability is expressed or observed in the invention. It is not clear whether, for example, the recited property of disrupting an OCH1 gene and introducing an alpha 1,2, mannosidase gene and expressing it, is sufficient for obtaining the recited property of producing a mammalian type sugar chain, and under what conditions it would do so.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
6/9/08